CLAIMS

What we claim is:

1. An immunogenic composition capable of producing a respiratory syncytial (RS) virus specific immune response in a host immunized therewith, comprising purified, inactivated RS virus which is substantially free from cellular and serum components and which is non-infectious, non-immunopotentiating, immunogenic and protective, and a carrier therefor.

2. The composition of claim 1 which is formulated as a vaccine for *in vivo* administration to a human host for protecting the human from a disease induced by RS virus.

3. The composition of claim 2 wherein said carrier further comprises an adjuvant.

4. The composition of claim 2 formulated to be administered in an injectable form, intranasally orally, or to mucosal surfaces.

5. A method of preparing a non-immunopotentiating, immunogenic composition capable of producing a respiratory syncytial (RS) virus specific immune response in a host immunized therewith, which comprises:

growing RS virus on a cell line to produce a grown virus;

harvesting said grown virus to produce a harvested virus;

purifying said harvested virus under non-denaturing conditions to produce a purified virus substantially free from cellular and serum components;

inactivating said purified virus with an inactivating agent to provide a non-infectious, non-immunopotentiating and immunogenic RS virus, and

formulating said non-infectious, non-immunopotentiating and immunogenic RS virus as said immunogenic composition.

6. The method of claim 5 wherein said inactivating agent is β-propiolactone.

7. The method of claim 5 wherein said inactivating agent is a non-ionic detergent.

8. The method of claim 7 wherein said non-ionic detergent is selected from the group consisting of n-octyl-α-D-glucopyranoside and n-octyl-β-D-glucopyranoside.

9. The method of claim 5 wherein said inactivating agent is ascorbic acid.

10. The method of claim 5 wherein said cell line is a continuous cell line of vaccine quality.

11. The method of claim 10 wherein said continuous cell line is a VERO cell line.

12. The method of claim 5 wherein said purifying step is effected by microfiltration to remove cell debris, tangential flow ultrafiltration to remove serum components, pelleting the ultrafiltered material by ultracentrifugation to further remove serum components, and subjecting the pelleted material to sucrose density gradient centrifugation.

13. The method of claim 12 wherein said tangential flow ultrafiltration is effected by employing an about 100 to about 300 kDa nominal molecular weight cutoff membrane.

14. The method of claim 5 wherein said purifying step is effected by microfiltration to remove cell debris, tangential flow ultrafiltration to remove serum components, gel filtration to further remove serum components, and ion-exchange chromatography to additionally remove serum components.

15. A method of immunizing a host against disease caused by respiratory syncytial virus, which comprises administering to the host an effective amount of the immunogenic composition of claim 1.

16. The method of claim 15 wherein said host is selected from infants, young children, pregnant women, women of child-bearing age, elderly individuals, immunocompromised individuals and susceptible persons.

17. A method of determining the presence of antibodies specifically reactive with respiratory syncytial (RS) virus proteins in a sample, comprising the steps of:

(a) contacting the sample with the immunogenic composition of claim 1 to produce complexes comprising the non-infectious, non-immunopotentiating and immunogenic RS virus and any said antibodies present in the sample specifically reactive therewith; and

(b) determining production of the complexes.

18. A method of determining the presence of respiratory syncytial (RS) virus proteins in a sample, comprising the steps of:

(a) immunizing a subject with the immunogenic composition of claim 1 to produce antibodies specific for RS virus proteins;

(b) contacting the sample with the antibodies to produce complexes comprising any RS virus proteins present in the sample and said RS virus protein specific antibodies; and

(c) determining production of the complexes.

19. A diagnostic kit for determining the presence of antibodies in a sample specifically reactive with RS virus proteins, comprising:

(a) the immunogenic composition of claim 1;

(b) means for contacting the non-infectious, non-immunopotentiating and immunogenic RS virus with the sample to produce complexes comprising the non-infectious, non-immunopotentiating and immunogenic RS virus and any said antibodies present in the sample; and

(c) means for determining production of the complexes.